IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ENEIDA LOPEZ	:	**CIVIL ACTION**
Plaintiff	:	
	:	**NO. 20-2694**
v.	:	
	:	
ETHICON INC., *et al*.,	:	
Defendants	:	

NITZA I. QUIÑONES ALEJANDRO, J. SEPTEMBER 16, 2020

MEMORANDUM OPINION

INTRODUCTION

Plaintiff Eneida Lopez filed this product liability action claiming injuries allegedly caused by a defective pelvic mesh implant device that was designed, manufactured, sold, and/or distributed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants"). This civil action was filed as part of the Multi-District Litigation ("MDL") pending in the United States District Court for the Southern District of West Virginia, *In Re: Ethicon Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327, and was subsequently transferred to this Court following the close of discovery.

Before this Court is Defendants' motion for summary judgment in which Defendants argue that all of Plaintiff's claims fail because, *inter alia*, either they are not recognized under Pennsylvania law or Plaintiff has failed to present evidence sufficient to meet her summary judgment burden. [ECF 31, 32]. In response, Plaintiff has withdrawn all of her claims except for the negligence and strict liability claims premised on failure to warn and design defect (Counts I, III, and V).[1] The issues raised by the parties have been fully briefed and are ripe for disposition.

[1] In her response, Plaintiff advises that she "will not proceed with" Count I (to the extent premised on a manufacturing defect) and Counts II, IV, and VI through XV. (Pltf. Resp. at 5). Therefore, these

For the reasons set forth herein, Defendants' motion is granted as to Counts III and IV, and denied as to her negligence claim at Count I. Judgment will be entered in favor of Defendants and against Plaintiff on Counts III and IV.

BACKGROUND

When ruling on a motion for summary judgment, a court must consider all record evidence and supported relevant facts in the light most favorable to the non-movant; here, Plaintiff. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Galena v. Leone*, 638 F.3d 186, 196 (3d Cir. 2011). Because the procedural and factual histories are known to the parties, only the facts pertinent to the underlying motion will be discussed. These facts are gleaned primarily from Plaintiff's statement of material facts. To the extent that any facts are disputed, such disputes will be noted and construed in Plaintiff's favor. The pertinent facts are as follows:

> On October 15, 2004, Plaintiff underwent surgical implantation of a TVT mesh device manufactured and designed by Defendants. The TVT mesh device was implanted by Dr. Eric C. Rittenhouse to correct stress urinary incontinence, from which Plaintiff suffered. Following the implant surgery, Plaintiff developed complications from the TVT mesh device including, *inter alia*, mesh erosion into the urethra, recurrent stress urinary incontinence, urinary urgency and frequency, urinary retention, and pelvic pain.[2] Due to her continuing symptoms, on January 26, 2016, Plaintiff underwent a surgical procedure that removed some of the TVT mesh device.
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> Despite this first corrective surgery, Plaintiff continued to suffer pelvic pain, vaginal pain, dyspareunia, and recurrent incontinence. As a result, in July 2017, Plaintiff had the remaining portion of the TVT mesh device excised and a fascial sling placed.

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claims are deemed withdrawn with prejudice. In addition, as Defendants correctly note, Count XVII (Punitive Damages) and Count XVIII (Discovery Rule and Tolling) are not independent claims under Pennsylvania law. As such, these claims are dismissed. Thus, only Plaintiff's negligence and strict liability claims premised on failure to warn and design defect (Counts I, III, and V) will be addressed herein.

[2] Defendants dispute that these complications were caused by their TVT mesh device or that the device was defective.

> Plaintiff has proffered the expert opinion of Bruce Rosenzweig, M.D., who opined that the warnings provided by Defendants to treating physicians, including Plaintiff's treating physician, in 2004, were inadequate in that they failed to communicate the risks associated with the device, and the severity and permanency of the potential complications. At this stage, Defendants have not challenged Dr. Rosenzweig's expert opinion.

LEGAL STANDARD

Federal Rule of Civil Procedure ("Rule") 56 governs summary judgment motion practice. Fed. R. Civ. P. 56. Specifically, Rule 56 provides that summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Id.* A fact is "material" if proof of its existence or non-existence might affect the outcome of the litigation, and a dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson*, 477 U.S. at 248. Under Rule 56, the court must view the evidence in the light most favorable to the nonmoving party. *Galena*, 638 F.3d at 196.

Pursuant to Rule 56, the movant bears the initial burden of informing the court of the basis for the motion and identifying those portions of the record which the movant "believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This burden can be met by showing that the nonmoving party has "fail[ed] to make a showing sufficient to establish the existence of an element essential to that party's case." *Id.* at 322. After the movant has met its initial burden, summary judgment is appropriate if the nonmoving party fails to rebut the moving party's claim by "citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials" that show a genuine issue of material fact or by "showing that the materials cited do not establish the absence

or presence of a genuine dispute." Fed. R. Civ. P 56(c)(1)(A)-(B). The nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986). The nonmoving party may not rely on "bare assertions, conclusory allegations or suspicions," *Fireman's Ins. Co. of Newark v. DuFresne*, 676 F.2d 965, 969 (3d Cir. 1982), nor rest on the allegations in the pleadings. *Celotex*, 477 U.S. at 324. Rather, the nonmoving party must "go beyond the pleadings" and "designate 'specific facts showing that there is a genuine issue for trial.'" *Id.* (citations omitted).

DISCUSSION

Plaintiff commenced this action by filing a short form MDL complaint in which she asserted numerous product liability claims premised on allegations of negligence, strict liability, fraud, and breach of warranty. After the close of discovery and before this case was transferred, Defendants moved for summary judgment on the majority of the claims. As noted, Plaintiff withdrew all of her claims except the negligence and strict liability claims premised on failure to warn and a design defect (Counts I, III, and V). Defendant argues that Plaintiff's strict liability claims are precluded under Pennsylvania law and that Plaintiff's negligence claims fail on account of Plaintiff's failure to present evidence sufficient to meet her burden regarding causation. Each of Defendants' arguments, and Plaintiff's responses thereto, are addressed below.

Strict Liability Claims

Defendants are manufacturers of medical devices, including the TVT pelvic mesh at issue. At Counts III and V, Plaintiff asserts claims against them for strict liability premised on a failure to warn and a design defect. Defendants move for summary judgment on these claims, arguing

that such claims are not legally viable against manufactures of medical devices under Pennsylvania law. This Court agrees.

As the parties and numerous courts have recognized, the Supreme Court of Pennsylvania has not yet decided whether Pennsylvania law recognizes strict liability claims against manufacturers of medical devices. The Supreme Court of Pennsylvania has, however, barred analogous strict liability claims against manufactures of prescription medications. *See Hahn v. Richter*, 673 A.2d 888, 891 (Pa. 1996). Here, this Court must predict whether the Supreme Court of Pennsylvania would, as a matter of law, recognize such a claim in the context of medical devices. *Orson, Inc. v. Miramax Film Corp*., 79 F.3d 1358, 1373 n.15 (3d Cir. 1996). In doing so, this Court must look to decisions of Pennsylvania's intermediate appellate courts and "accord [them] significant weight in the absence of an indication that the highest state court would rule otherwise." *Id.* For the reasons discussed below, this Court predicts that the Supreme Court of Pennsylvania would apply its holding in *Hahn* to medical devices, such as the device at issue here.

The Supreme Court of Pennsylvania has adopted the strict liability formulation set out in § 402A of the Restatement (Second) of Torts. *Tincher v. Omega Flex, Inc.*, 104 A.3d 328, 394-99 (Pa. 2014). Under Pennsylvania law, there are three different types of defects that give rise to a strict liability claim: (1) design defect; (2) manufacturing defect; and (3) warning defect (*i.e.*, failure to warn or inadequate warnings). *See Phillips v. A-Best Prods. Co.*, 665 A.2d 1167, 1170 (Pa. 1995); *Doughtery v. C.R. Bard*, 2012 WL 2940727, at *2 (E.D. Pa. July 18, 2012). In *Hahn*, the Supreme Court of Pennsylvania adopted Comment k to § 402A and held that it bars strict liability claims against a prescription drug manufacturer where a prescription drug is at issue. 673 A.2d at 891. Specifically, Comment k limits liability for "[u]navoidably unsafe products" and provides as follows:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A cmt. k (emphasis in original).

Relying on Comment k and its' previous decisions involving liability of prescription drug manufacturers, the Supreme Court of Pennsylvania held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." *Hahn*, 673 A.2d at 891; *see also Lance v. Wyeth*, 85 A.3d 434, 438 (Pa. 2014) (reaffirming its holding in *Hahn* that Comment k bars strict liability for prescription drug manufacturers). Pennsylvania lower courts have since applied Comment k to bar strict liability theories based on a failure-to-warn, as well as a design defect theory. *See*, *e.g.*, *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006). As noted and argued by Plaintiff, however,

Comment k speaks in terms of prescription drugs—it does not specifically mention medical devices. Although the Supreme Court of Pennsylvania has not yet addressed the distinction, the Superior Court of Pennsylvania has, and explained that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (affirming the determination that Comment K barred plaintiffs' strict liability claim for medical device). The *Creazzo* Court also explicitly rejected the plaintiffs' argument that Comment k should not apply "to medical devices because the comment text does not mention them[,]" *id.*, reasoning that there was no authority "for so restrictive an interpretation either of comment k or of *Hahn*." *Id.*

Federal courts faced with the same issue of Pennsylvania law have unanimously held that Comment k applies to medical devices, thus, barring strict liability design defect and failure-to-warn claims. *See*, *e.g.*, *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 575, 577 (E.D. Pa. 2019) (dismissing strict liability claims related to medical device); *Smith v. Howmedica Osteonics Corp.*, 251 F. Supp. 3d 844, 848 (E.D. Pa. 2017) (dismissing strict liability design defect claim related to medical device); *Carson v. Atrium Med. Corp.*, 191 F. Supp. 3d 473, 477 (W.D. Pa. 2016) (dismissing plaintiff's strict liability failure to warn claim related to polypropylene hernia mesh); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 833 (E.D. Pa. 2016) (concluding "Comment k's prohibition of strict liability-design defect and strict liability-failure to warn claims for prescription drugs should also apply to medical devices."); *Runner v. C.R. Bard, Inc.*, 108 F. Supp. 3d 261, 266 (E.D. Pa. 2015) (dismissing strict liability claims relating to mesh based on Comment k); *Kee v. Zimmer*, *Inc.*, 871 F. Supp. 2d 405, 410 (E.D. Pa. 2012) (dismissing strict liability failure to warn claim related to medical device); *McPhee v. DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 461 (W.D. Pa. 2012) (dismissing strict liability failure to warn claim and design

defect claims against medical device manufacturer pursuant to Comment k); *Soufflas*, 474 F. Supp. 2d at 750 (dismissing design and failure to warn strict liability claims and predicting Pennsylvania Supreme Court would adopt Comment k for medical devices); *Parkinson v. Guidant Corp.*, 315 F. Supp. 2d 741, 747 (W.D. Pa. 2004) (dismissing strict liability design and failure to warn claims against medical device manufacturer); *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 442 (E.D. Pa. 2004) ("Comment k precludes application of Section 402A to prescription medical devices."); *see also Atkinson v. Ethicon, Inc.*, 2019 WL 3037304, at *5 (W.D. Pa. July 11, 2019) (determining strict liability failure to warn and design defect claims were barred by Pennsylvania law); *Buck v. Endo Pharm., Inc.*, 2019 WL 1900475, at *8 (E.D. Pa. Apr. 29, 2019) (concluding "strict liability design defect and failure to warn claims under Pennsylvania law fail."); *Wallace v. Bos. Sci. Corp.*, 2018 WL 6981220, at *6-7 (M.D. Pa. Nov. 29, 2018), *R & R adopted by*, 2019 WL 137605 (M.D. Pa. Jan. 8, 2019) (dismissing strict liability design defect and failure to warn claims related to implantation of mesh device based on Comment k).

While not bound by these cases, this Court agrees and is persuaded by them and by the Superior Court of Pennsylvania's analysis in *Creazzo*. The language in Comment k is not strictly limited; it applies to "other drugs, vaccines, and the like, many of which . . . cannot legally be sold except to physicians, or under the prescription of a physician." Like prescription drugs, medical devices generally are sold through a physician, are directed to the treatment of specific medical conditions, and have unquestioned benefits that may outweigh the risk of potential harm. Based on the aforementioned cases, this Court predicts that the Supreme Court of Pennsylvania will likely hold, for the same policy reasons cited in *Hahn* and *Creazzo*, that the arguments regarding prescription drugs apply equally to medical devices, such as the TVT pelvic mesh implant at issue here.

Additionally, Plaintiff fails to cite any case law allowing either a strict liability design defect or a failure to warn claim to proceed under Pennsylvania law with respect to a medical device.[3] Instead, Plaintiff cites to the Supreme Court of Pennsylvania's decision in *Tincher* for the broad proposition that "[n]o product is expressly exempt" from strict liability. 104 A.3d at 382. Plaintiff's argument is misguided. In *Tincher*, homeowners brought an action against the manufacturer of stainless-steel tubing. *Id.* at 335-36. Notably, *Tincher* did not involve a prescription drug or medical device, and the Court did not overrule *Hahn* or *Lance*, even though the opinion expressly overruled another Pennsylvania Supreme Court opinion. In fact, the *Tincher* Court specifically noted an exception to the cited general proposition by immediately following this broad statement with a "but see" citation to *Hahn*, signaling that "where adequacy of warnings associated with prescription drugs is at issue, strict liability is not recognized as basis for liability." *Id.* at 362 n.13.

Thus, the *Tincher* decision does not reflect any regression or retreat from, or limitation to, the Supreme Court of Pennsylvania's decision in *Hahn*. Like every court to have considered this

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[3] Plaintiff cites to *Beard v. Johnson & Johnson, Inc*., 41 A.2d 823 (Pa. 2012), to support her contention that "in the twenty years since *Hahn*, strict liability claims against medical device manufacturers have proceeded in Pennsylvania." (Pltf.'s Resp. at 8). However, unlike the medical device at issue here, the device in *Beard* was a tool *used by* medical professionals to perform surgical procedures—it was not a medical device *implanted* inside the body for the purpose of treating a medical condition. *Id*. at 824-25. As such, the *Beard* decision is inapposite and does not diminish the likely extension of *Hahn* to medical devices such as that at issue here.

Plaintiff also cites to a number of federal district court decisions evidencing a split among federal courts as to whether a claim for strict liability based on a manufacturing defect, a claim Plaintiff has withdrawn, would also be barred. *See Wagner v. Kimberly-Clark Corp.*, 225 F. Supp. 3d 311, 316 (E.D. Pa. 2016); *Bergstresser v. Bristol-Myers Squibb Co*., 2013 WL 1760525, at *2 (M.D. Pa. Apr. 24, 2013); *Wallace v. Boston Scientific Corp*., 2018 WL 6981220, at *6 (M.D. Pa. Nov. 29, 2018); *Atkinson*, 2019 WL 3037304, at *5, ("As to strict liability, there is a split among federal district courts applying Pennsylvania law as to whether strict liability is an available cause of action against the manufacturer of a medical device; yet, even under the most permissive interpretation, such claims exist only with respect to manufacturing defects in medical devices and not with respect to other theories of strict liability."). Since Plaintiff has withdrawn her strict liability manufacturing claim, this Court need not address the split here.

issue, this Court concludes that Plaintiff's strict liability claims premised on design and warning defects for a medical device are not legally viable under Pennsylvania law. Accordingly, Defendants' motion for summary judgment as to these claims (Counts III and V) is granted.

Negligence Claims (Failure to Warn and Design Defect)

At Count I, Plaintiff asserts negligence claims premised on Defendants' defective design and failure to warn.[4] Defendants move for summary judgment on the failure to warn claim on the basis that Plaintiff has not provided requisite evidence of causation to sustain her claim. Specifically, Defendants argue that the undisputed evidence shows that Plaintiff's treating physician did not rely on the warnings included within the product's packaging and, thus, Plaintiff cannot show that the outcome would have been different had Defendants included the additional warnings that Plaintiff contends should have been required. Because this Court finds that there are genuine issues of disputed fact as to causation, Defendants' motion for summary judgment on Count I is denied.

To establish a negligent failure to warn claim in Pennsylvania, a plaintiff must demonstrate that the defendant breached its duty to warn, and that the breach caused her injuries. *Demmler v. SmithKline Beecham Corp.*, 671 A.2d 1151, 1155 (Pa. Super. Ct. 1996); *Soufflas v. Zimmer, Inc.,* 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007). In the context of a claim alleging failure to warn regarding the risks of a medical device, the manufacturer's duty is to adequately warn the treating physician, *i.e.*, the learned intermediary. *Simon v. Wyeth Pharm.*, 989 A.2d 356, 368 (Pa. Super. Ct. 2009); *see also Demmler*, 671 A.2d at 155 ("In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must further establish proximate causation by showing that had defendant issue a proper warning to the learned

[4] Notably, Defendants have not moved for summary judgment on Plaintiff's negligent design claim, included within Count I.

intermediary, he would have altered his behavior and the injury would have been avoided.") (citation omitted).

With respect to causation, a plaintiff must establish legal cause—that the failure to warn was a "substantial contributing factor" to the harm she suffered. *Gurley v. Janssen Pharmaceuticals, Inc.*, 113 A.3d 283, 292 (Pa. Super. Ct. 2015). In other words, a plaintiff must demonstrate that, had the manufacturer issued a proper warning, "he would have altered his behavior and the injury would have been avoided." *Id*. "To create a jury question, the evidence introduced must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug, or in this case, the mesh device." *Cochran v. Wyeth, Inc*., 3 A.3d 673, 676-77 (Pa. Super. Ct. 2010), *appeal denied*, 20 A.3d 1209 (Pa. 2011).

A plaintiff must also establish proximate causation. In order to prove proximate causation under the learned intermediary doctrine, which applies here, the plaintiff asserting a claim against a medical device manufacturer must "show that with a different warning, the prescribing doctor would have changed his prescribing practices, *and* the plaintiff's injury would have been avoided." *Bock v. Novartis Pharm. Corp*., 137 F. Supp. 3d 802, 808 (W.D. Pa. 2015) (citations omitted) (emphasis in original); *see also Demmler*, 671 A.2d at 1155 (holding "plaintiffs must . . . establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided."). "[S]ummary judgment is properly granted on a failure to warn claim where the record 'is devoid of evidence to support [the] argument that a different warning would have altered [the physician's] prescribing methods . . . .'" *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 639 F.

App'x 874, 878 (3d Cir. 2016) (alterations in original) (quoting *Lineberger v. Wyeth*, 894 A.2d 141, 150 (Pa. Super. Ct. 2006).

Here, Defendants argue that Plaintiff has failed to meet, and cannot meet, her summary judgment burden on causation because her treating physician purportedly "did not rely on Ethicon's warning." (Defs. Br. at 8). In support of this contention, Defendants cite the following testimony of Plaintiff's treating physician, Dr. Rittenhouse:

> Q. In the course of your career you treated with Dr. Lucente to find out about how to implant the TVT. I am assuming that you have had discussions with sales reps about the TVT. Are you familiar with the instructions for use for the TVT or, I believe, some doctors sometimes call it the package insert?
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> A. I am familiar with it, yes.
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> Q. Have you read it?
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> A. I know that I have looked at it, but not in -- I mean, back then, probably. I routinely review stuff like that. I know I have read it in -- later, I read it. I know I read it thoroughly only because in -- the malpractice company that I had for insurance about eight years ago required us to -- I actually wrote a specific consent for them, which they now use for all of their physicians doing it. They asked me to do it. They wanted a specific consent that went through all of the language, and I wrote that up for them. It's a four-page document, but it included all of the FDA that they wanted in there, that somebody was really, kind of, signing that they understood -- you know, once we learned of some of the other difficulties that happened, but back in 2004, that didn't exist. I mean, that wasn't a practice that I was doing.

Contrary to Defendant's bald assertion, this testimony does not unequivocally establish the Dr. Rittenhouse did not rely on the warnings contained in the device packaging. In fact, if indicative of anything, this testimony shows that Dr. Rittenhouse *did* have a practice of reading the warnings included in the packaging. This testimony creates a genuine issue of material fact as to whether Dr. Rittenhouse relied on the warnings provided with respect to his treatment of Plaintiff, such that he would or would not have altered his prescription of the TVT mesh device had Defendants

provided additional, adequate warnings.[5] Accordingly, because genuine issues of material fact exist, Defendants' motion for summary judgment as to Plaintiff's negligent failure to warn claim is denied.

CONCLUSION

For the reasons stated herein, this Court finds that Plaintiff's remaining strict liability claims (Counts III and V) are barred by Pennsylvania law consistent with the reasoning and analysis of the Supreme Court of Pennsylvania in *Hahn*. Accordingly, Defendants' motion for summary judgment is granted as to these claims, and judgment is entered in favor of Defendants and against Plaintiff on Counts III and V.

In addition, because this Court finds that genuine issues of material fact exist with respect to causation, Defendants' motion is denied with respect to Plaintiff's remaining negligence claims (Count I). An Order consistent with this Memorandum Opinion follows.

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[5] The cases cited by Defendants to support their contention that Plaintiff's physician did not rely on the warnings (*see* Defs. Br. at p. 8 n.12) are also distinguishable from the facts presented here. In each of the cited cases, the treating physician testified that he or she had ***never read*** the manufacturer's warnings for the devices at issue. Here, to the contrary, Dr. Rittenhouse testified that he read and was familiar with the warnings provided.